Military Specification Anodic Coatings for Aluminum and Aluminum Alloys and over Applicant's statement of the prior art.

Claims 21-36, 39-42, 55, 64, and 73-74 are rejected provisionally for obviousness double patenting over US 6,589,477 in view of Feldman and the Military specification..

Claims 21-36, 39-42, 55, 64, and 73-74 are rejected provisionally for obviousness double patenting over co-pending application US 10/295,758.

Claims 21-23, 27-36, 39-42, 55, 64, and 73-74 are presented for reconsideration.

REMARKS

In summary form., the rejection now outstanding were previously made and Applicant responded thereto relying in part on the prior Declaration of Marcia Frieze. The Examiner criticized the prior Response in that she characterized the prior Frieze Declaration as merely statements without any data or concretely demonstrated evidence.

Enclosed herewith, Applicant submits a new Declaration by Marcia Frieze. This Declaration reports the data on sterilization efficacy shown by using sterilization containers of the present invention (tests performed in 2000) vs using containers that are beyond the present invention claims (tests in 2006) using (a) containers that are the same as in the prior test but modified to have an anodization coating of 1mil and (b) a competitor container having an anodization coating of 2-3mil.

In the 2000 testing, all of the containers used accomplished sterilization of the substrates contained therein using a STERRAD 100S Sterilizer in a Half Cycle Mode. None of the substrates showed any contamination whatsoever. This is extremely important since in real world use, the sterilization is being conducted on medical instruments and contamination with infectious agents is simply not an acceptable result, even small contamination.

In the 2006 testing where the invention containers were modified to have anodized coatings of 1 mil, i.e. in excess of the claim limitation of "substantially not more than 0.5

mil", and containers from a competitor having 2 mil to 3 mil thick anodized coatings, none of the substrates that were contained in the containers and none of the substrates that were in permeable peel packs outside of the containers achieved sterility. This was so despite the STERRAD 100S Sterilizer fail safe abort and warning system of non-sterilization not triggering. In addition, the conditions of the 2006 system differed in a few respects from the 2000 testing, but all of those differences would lead one to conclude that the 2006 testing protocol would achieve a higher kill rate than in 2000. Since the 2000 testing had no contamination, if there was no critical difference between the containers in the 2000 test and those in the 2006 test, one would have expected zero contamination. Nonetheless, not one of the inoculated substrates, whether in or out of the containers achieved sterility. Thus, not only is the anodized thickness limitation of the claims an important and critical one to achieve sterility of contaminated substrates placed in such containers for sterilization, but the mere placement of containers having anodization layers in excess of those of the claims leads to failure of sterilization of substrates placed in the sterilizer at the same time, but not in those containers.

Thus, it is clear that the "substantially not in excess of 0.5 mils" limitation of the present invention claims is a critical limitation.

As stated above, the Examiner continued to rejected the claims because the prior Frieze Declaration was characterized as merely statements without the presentation of data or objective evidence as to the criticality of the limitation. The present Frieze Declaration submits the requested data and objective evidence, which shows the unexpected nature of the invention limitations.

The Examiner also entered a new rejection of the claims over Deeds in view of Miller, Feldman, the Military Specification, and Applicant's statement of the State of the Art. Deeds, Miler, and Feldman were all part of the prior rejection. The reliance on the Military Specification and the "Applicant's statement of the state of the art" are new to the rejection. The Examiner acknowledges that Miller and Feldman are silent as to the

thickness of the anodized coat. The Examiner asserts that those references indicate the layer is thin and then relies on the military Specification for a teaching of a "standard" specification of anodized aluminum coatings of up to 0.7 mils. It should be noted that many of the competitor sterilization container products for use in plasma sterilization that have anodic coatings have substantially thicker coatings. For example, the Genesis product that was used in some of the tests in the accompanying Frieze Declaration utilize an anodic coating of 2 mil to 3 mil. Thus, it is not at all obvious to one of ordinary skill to utilize a coating of substantially not in excess of 0.5 mil, even though preparation of aluminum with the claimed range of anodic coating is possible. The question is what motivates one to make the combination that the Examiner suggests, without the use of hindsight. Here there is nothing but the suggestion of a thin coating from the primary references. The Military Specification indicates certain coating thicknesses on aluminum are possible, but there is no suggestion that the use of the Military Specification range should be used or that the unexpected results as demonstrated by the Frieze Declaration would or could be achieved.

Furthermore, the Military Specification has ranges of anodic coatings that are much broader and there is no indication which one should be used. Note that at page 17, in table IV, there are ranges that go up to 4.5 mil. One range is from 0.02 to 0.7 mil, a second range is from 0.07 mil to 1 mil, the third range is from 0.5 mil to 4.5 mil. It cannot be overstated that all of these are thin coatings. All that the Military Specification provides is that the anodic thickness desired for the invention is technically possible. It does not give any guidance as to why one should avoid exceeding 0.5 mils. The present invention is precisely that for sterilization containers for use in plasma sterilization contexts, one should use an anodization layer that is substantially not in excess of 0.5 mils. The references, alone and in combination do not provide such direction to those of ordinary skill, and certainly one of ordinary skill would not have expected there to be any criticality about that limitation in the absence of the present application text as a guide.

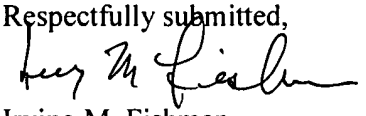
Thus, the current rejection under 35 USC 103 is overcome.

The only remaining rejections are Obviousness Double Patenting rejections. The first one relies on a combination of US 6,589,477 Feldman and the Military Specification. This obviousness double Patenting rejection is overcome for the same reasons as the 35 USC 103 rejection is overcome. Here the '477 patent does not have the anodization thickness limitation and the examiner is relying on the other references to supply that limitation. For the same reasons set forth above, the anodization layer thickness is not an obvious choice, but rather is an unobvious one, being tied to unexpected properties. Thus, the obviousness Double patenting rejection on this ground is overcome.

The second obviousness Double Patenting rejection is over copending application 10/295,758. Applicant defers action on this until such time as all other issues in this case are resolved in favor of allowance. At that time, Applicant reasserts that Applicant will either (1) cancel any claims from one of these two application which are obvious over the other or (b) will file a Terminal Disclaimer. Either of these actions will overcome the rejection.

As there are no further outstanding rejections, Applicant submits the present case is in condition for allowance (other than the action to be taken on the Obviousness Double Patenting issue over US 10/295,758). An indication of allowable subject matter is respectfully requested.

Respectfully submitted,



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